Dated: April 15, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

The National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) Announces the Following Public Meetings

Name: Update on Hanford Thyroid Disease Study Draft Final Report.

Dates: Wednesday, May 5, 1999, Thursday, May 6, 1999

Times: 7 p.m.–9 p.m., 7 p.m.–9 p.m.

Place: WestCoast Ridpath Hotel, West 515 Spraque, Spokane, Washington 99201,

*Tel: (*509) 838–2711, Doubletree Hotel Seattle Airport, 18740 Pacific Highway South, Seattle, Washington 98188, (206) 246–8600.

Status: Open to the public, limited only by the space available. The meeting room will accommodate approximately 200 people.

Purpose

The CDC and investigators from Seattle's Fred Hutchinson Cancer Research Center (FHCRC) will discuss findings on the Hanford Thyroid Disease Study Draft Final Report. The purpose of the study was to determine if there was an increased risk for thyroid disease among a randomly selected study population exposed to atmospheric releases of radioactive iodine-131 (I–131) from the Hanford Nuclear Site in eastern Washington State during the 1940s and 1950s. The study, mandated by Congress, was conducted by a team of scientists at the FHCRC under contract from the CDC.

Background

In 1986, Freedom of Information Act requests led the Department of Energy to make public thousands of pages of documentation indicating that large quantities of radioactive materials were released into the atmosphere from the Hanford Nuclear Site. The radioactivity was a byproduct of nuclear weapons production from December 1944 through 1957. Most of the radioactivity was released in the form of I–131, which concentrates in the thyroid glands of those who eat food contaminated by it. The amount of I–131 released during this period was more than half a million curies, prompting concern regarding thyroid health effects. The government convened a special Hanford Health Effects Review Panel to review the documents and recommend steps to evaluate possible health consequences among those who live near the Hanford Site.

Two studies were undertaken as a result of these recommendations. The first was the Hanford Environmental Dose Reconstruction Project which estimated potential radiation doses to the thyroid among persons exposed to Hanford I–131 releases. The second was the Hanford Thyroid Disease Study. This study was designed to determine whether the exposures from Hanford resulted in an increased risk of thyroid disease in a randomly selected study population. In late 1989, a contract to perform this study was awarded to the FHCRC.

CONTACT PERSONS FOR ADDITIONAL INFORMATION: General information may be obtained from Mr. Mike Donnelly, Project Officer, Radiation Studies Branch (RSB), Division of Environmental Hazards and Health Effects (DEHHE), NCEH, CDC, 4770 Buford Highway, NE, M/S (F–35), Atlanta, Georgia 30341–3724, telephone 770–488–7040, fax 770–488–7044. Technical information may be obtained from Dr. Paul Garbe, RSB, DEHHE, NCEH, CDC, 4770 Buford Highway, NE, (F–35), Atlanta, Georgia 30341–3724, telephone 770–488–7040, fax 770–488–7044.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 15, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office Centers for Disease Control and Prevention (CDC).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0674]

Draft Guidance for Industry on IND's for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products; Chemistry, Manufacturing, and Controls Content and Format; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''INDs for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products; Chemistry, Manufacturing, and Controls Content and Format.'' This draft guidance is intended to provide recommendations to sponsors of investigational new drug applications (IND's) on the chemistry, manufacturing, and controls documentation (CMC), including microbiology documentation, that should be submitted for phase 2 and 3 of IND's. This draft guidance applies to human drugs and specified-biotechnology derived products.

DATES: Written comments on the draft guidance document may be submitted by July 20, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance for industry to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Charles P. Hoiberg, Center for Drug Evaluation and Research (HFD–810), Food and Drug